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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,910	01/12/2006	Jonathan Alexander Terrett	2543-1-040PCT/US	1458

23565 7590 07/10/2009
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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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07/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,910	Applicant(s) TERRETT, JONATHAN ALEXANDER	
	Examiner ANNE L. HOLLERAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim 42 is added.

Claims 33-42 are pending and examined on the merits.

Claim Rejections Maintained and New Grounds of Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detection of PTK7 polypeptides comprising or consisting of the amino acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for methods of detection of a PTK7 polypeptide that is a derivative having at least 70% identity to SEQ ID NO:1 or a fragment at least 100 amino acids in length having at least 70% homology over the length of the fragment to SEQ ID NO: 1, where the methods have the use of screening for and/or diagnosis or prognosis of carcinoma selected from breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma in a subject, and/or monitoring the effectiveness of carcinoma therapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these

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claims. The basis for this rejection is that the specification fails to establish that the genus of PTK7 polypeptides as defined in the claims is associated with breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma.

New grounds of rejection are presented.

Applicants state that claim 33 has been amended to define that the PTK7 polypeptide comprises or consists of the amino acid sequence of SEQ ID NO: 1, or a derivative having at least 70% identity to SEQ ID NO: 1, or a fragment of at least 100 amino acid in length having at least 70% homology over the length of the fragment to SEQ ID NO: 1. Applicants state that the definition of the exact nature of the biological activity of PTK7, including whether it functions as an active or inactive tyrosine kinase, is not necessary for a method of screening or diagnosis comprising detection of PTK7 in order to meet the requirement for enablement, and that the present inventors have found an increase of PTK7 expression in certain carcinomas including breast cancer, lung cancer, kidney cancer, bladder cancer and pancreatic cancer, thereby demonstrating at least that PTK7 may be used as a marker for screening or diagnosis of these cancers as claimed.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

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Applicants' arguments have been carefully considered, but fail to persuade. The specification provides support for methods the claimed methods to the extent the PTK7 is defined as comprising or consisting of SEQ ID NO: 1. The specification describes experiments using an antibody that recognizes two peptides constructed from the amino acid sequence of SEQ ID NO: 1. In the experiments the antibody detects differential expression in a number of different cancer cells of a protein that appears to be identified as a protein consisting of the amino acid sequence of SEQ ID NO: 1, because the specification describes the use of MALDI to determine a partial amino acid sequence that when compared with sequence databases matches with Accession No. JC4593 (which appears to be a sequence having the same sequence as SEQ ID NO: 1). This disclosure in the specification demonstrates that PTK7, to the extent that it is a protein consisting of the amino acid sequence of SEQ ID NO: 1, is associated with several different cancer types, of which breast, pancreatic, lung, bladder or kidney, or osteosarcoma, are included. However, this disclosure fails to enable the use methods of detection for species of PTK7 other than one that consists or comprises the amino acid sequence of SEQ ID NO: 1. Although assays may be constructed for detecting species of PTK7 that are within the broadly defined genus recited in claim 33, there is no disclosure in the specification or the prior art associating any species other than the PTK7 species that consists of the amino acid sequence of SEQ ID NO: 1 with any type of cancer, or with the cancers recited in the claimed methods. The association of a particular protein or its variant with any type of cancer is not a predictable event. There is no reason provided in the specification or in the prior art which may be used as a basis to extrapolate from the results showing that detection of the amino acid sequence of SEQ ID NO:

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1 and its association with certain cancers to the broadly claimed methods where the detection of variants and fragments are included in the scope of the claims.

Because of the limited guidance provided by the specification and because of the inherent unpredictability in the association between a particular protein and the presence of a particular cancer, the broad scope of the claims is not fully supported by the specification. It would require undue further experimentation to practice the broadly claimed inventions because although the techniques for protein detection are well known, there is no guidance in the specification for the detection of the full range of PTK7 species encompassed by the claims for the purpose of detecting breast, pancreatic, lung, Bladder, or kidney cancer, or osteosarcoma.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-42 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by Hess-Stump (US 6,780,594; Aug. 24, 2004; effective filing date Oct. 26, 2000).

Applicants' arguments have been carefully considered, but fail to persuade. Applicants argue that Hess-Stump does not detect any of the cancers recited in the claims. However, Hess-Stump teaches the active method steps of the claims. The detection of the specific cancers is an

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intended use of the claimed methods that fails to limit the active steps of the claims because the claims are drawn to detection of PTK7 in a biological sample from any subject.

Claims 33-42 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by Mack (US 7,189,507; Mar. 13, 2007; effective filing date Apr. 12, 2002).

Applicants' arguments have been carefully considered, but fail to persuade. Applicants argue that Mack does not detect any of the cancers recited in the claims. However, Mack teaches the active method steps of the claims. The detection of the specific cancers is an intended use of the claimed methods that fails to limit the active steps of the claims because the claims are drawn to detection of PTK7 in a biological sample from any subject.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
July 6, 2009
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643